

REMARKS

In the aforesaid Office Action, claims 14, 27 and 32 were objected to under 35 USC 132 as introducing new matter and rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement, claims 1-3, 5, 7-11, 14-19, 21-24, and 26-29 were rejected under 35 USC 103(a) as being unpatentable over Chen et al. (5,849,846) in view of Sun et al. (5,728,748), and claims 12, 20, and 30-35 were rejected under 35 USC 103(a) as being unpatentable over Chen et al. in view of Sun et al. and further in view of Lee et al. (WO 99/13924). Claims 1-3, 5, 7-12, 14-24 and 26-35 are pending.

The Examiner objected to claims 14, 27 and 32 under 35 USC 132 as introducing new matter and rejected the claims under 35 USC 112, first paragraph as failing to comply with the written description requirement, stating that the limitation “so that the electron-beamed balloon has a second rupture pressure equal to *or not greater than* the first rupture pressure (italicized portion) is not supported by the disclosure”. Applicants have amended claims 14, 27 and 32 to call for the second rupture pressure being equal to or less than the first rupture pressure. The Examiner’s attention is directed to page 14, lines 13-22, disclosing an Example which makes it clear that the terminology “not more than about x% less than” as used in Applicant’s specification means *less than* by not more than x%. Specifically, the Example on page 14 discloses that a second rupture pressure of at least about 15 to about 20 atm, and specifically of about 17 to about 20 atm, is “not more than about 15 to about 25 percent less than” the first rupture pressure of

about 20 atm. It should be noted also that although the Example discloses that the second rupture pressure is at least 15 atm, it disclose that the second rupture pressure is specifically about 17-20 atm and does not disclose that it is at least 20 atm (i.e., it does not disclose that the second rupture pressure is greater than or at least equal to the first rupture pressure). As a result, the specification discloses a second rupture pressure which is one of the two alternatives of equal to or less than the first rupture pressure, and therefore discloses a second rupture pressure which is not greater than the first rupture pressure.

The Examiner rejected claims 1-3, 5, 7-11, 14-19, 21-24, and 26-29 under 35 USC 103(a) as being unpatentable over Chen et al. (5,849,846) in view of Sun et al., and claims 12, 20, and 30-35 under 35 USC 103(a) as being unpatentable over Chen et al. in view of Sun et al. and further in view of Lee et al., stating with regard to claims 1-3, 5, 7-9, 11, 14, 15, 21-24 and 26-29 that Sun et al. teaches a method of sterilizing a medical implant wherein the implant is placed within an air-tight container, and the container evacuated and then repressurized with an inert gas within a sealed chamber, and that in doing so with the catheter of Chen et al., the step of evacuation (of the container from Sun et al.) would purge the oxygen/air from the interior of the catheter and the step of repressurizing the sealed container with an inert gas would fill the catheter of Chen et al. with the inert gas.

However, Chen et al. in view of Sun et al. does not disclose or suggest purging the medical device component before it is placed in the container, as required by claims 1

and 17, or purging the container with the already purged balloon catheter therein as required by claims 21 and 33. Instead, Sun et al. discloses evacuating and repressurizing the container with inert gas and the Examiner asserts that evacuating and repressurizing the container with inert gas would evacuate and fill the catheter of Chen et al. with inert gas.

Regarding claims 14, 27 and 32, the Examiner states that as Chen teaches that the burst pressure is increased, then the second rupture pressure is not significantly less than the first rupture pressure. However, Chen does not disclose or suggest a balloon in which the second rupture pressure is equal to or less than the first rupture pressure as required by claims 14, 27 and 32. Instead, Chen specifically requires irradiating the catheter balloon to increase the burst pressure and fatigue strength of the balloon (see col. 9, lines 20-25).

Moreover, regarding claim 34, the combination of Chen et al. with Sun et al. in view of Lee et al. does not disclose or suggest applying an electron beam to the balloon catheter without forming reactive radicals upon exposure to the electron beam. Rather, Sun et al. discloses first creating free radicals by irradiating the material and then forming cross-links between said free radicals using heat (see claim 9, and col. 3, line 49 to col. 4, line 13). Support for claim 34 can be found in paragraph [3] of the Summary section of Applicant's specification.

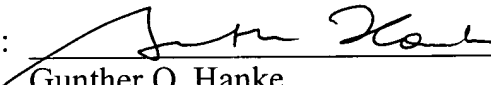
In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824 5555 to facilitate prosecution of this application, if necessary.

Applicants respectfully request that the Examiner review the references cited in the Form PTO/SB/08B submitted March 4, 2004 (copy attached) and return a copy of the initialed form to the attention of the undersigned.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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